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Vista IP Law Group LLP
2040 MAIN STREET, Suite 710
IRVINE, CA 92614

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte SURESH S. PAI,
CELSO J. BAGAOISAN, and FARHAD KHOSRAVI

_____

Appeal 2010-008125
Application 10/982,385
Technology Center 3700

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Before DEMETRA J. MILLS, ERIC GRIMES, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to an apparatus for sealing a puncture extending through living tissue. The Examiner entered rejections for obviousness.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Appellants' invention is directed to an apparatus for sealing puncture wounds which can result from procedures that access a patient's vasculature percutaneously; "[f]or example, a hollow needle may be inserted through a

patient's skin and overlying tissue into a blood vessel. A guide wire may be passed through the needle lumen into the blood vessel, whereupon the needle may be removed" (Spec. [0002]). After needle removal, an "introducer sheath may then be advanced over the guide wire into the vessel, e.g., in conjunction with or subsequent to one or more dilators" allowing access to the vessel for the purpose of performing medical procedures (*id.*).

Claims 1, 3-28, 31-40, and 60-70 stand rejected and appealed (App. Br. 2).[1] Claim 1 is representative and reads as follows:

> 1. An apparatus for sealing a puncture extending through tissue, comprising:
>
> a tubular member comprising a proximal end, a distal end sized for insertion through the puncture, a lumen extending between the proximal and distal ends, and a distal opening in communication with the lumen;
>
> a bioabsorbable plug disposed within the lumen and comprising a lumen extending between proximal and distal ends thereof, the plug comprising hydrogel;
>
> a bioabsorbable anchor element disposed within the lumen proximal to the plug;
>
> a pusher member slidable within the lumen of the tubular member for deploying the plug and anchor element through the lumen and out the distal opening of the tubular member; and
>
> an elongate positioning member, the positioning member having an expandable element on a distal end thereof, the positioning member sized for slidably passing through the lumen of the tubular member and the lumen of the plug.

The following rejections are before us for review:

(1) Claims 1, 3-14, 21-28, 31-40, and 60-70, under 35 U.S.C. § 103(a) as obvious over Cates,[2] Sawhney,[3] and Zhu[4] (Ans. 3-5); and

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[1] Appeal Brief entered November 3, 2009.
[2] U.S. Patent No. 6,162,240 (issued December 19, 2000).

(2) Claims 15-20, under 35 U.S.C. § 103(a) as being obvious over Cates, Sawhney, Zhu, and Vidal[5] (Ans. 5-6).

DISCUSSION

The Examiner found that Cates described an apparatus substantially as claimed, except that Cates' device did not have a plug composed of hydrogel, and also did not have a bioabsorbable anchor proximal to its plug, as recited in independent claims 1, 28, and 60 (Ans. 3-4). The Examiner concluded, however, that modifying Cates' device to include those features would have been prima facie obvious, in view of the teachings of Sawhney and Zhu that such features were known to be useful on devices of the type described by Cates (*id.*).

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992).

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), while the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question, it also reaffirmed the importance of determining "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue." *Id.* at 418 (emphasis added).

Thus, "[o]bviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim

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[3] U.S. Patent No. 6,605,294 B2 (issued August 12, 2003).
[4] U.S. Patent App. Pub. No. 2002/0072767 A1 (published June 13, 2002).
[5] U.S. Patent No. 5,334,216 (issued August 2, 1994).

under examination." *Unigene Laboratories, Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011).

We agree with Appellants that the Examiner has not shown that the cited references would have rendered the claimed apparatus prima facie obvious to an ordinary artisan. In particular, we agree with Appellants that the Examiner has not adequately explained why the cited references would have suggested including Zhu's bioabsorbable anchor in Cates' device, proximal to Cates' bioabsorbable plug, as the claims require.

Specifically, claim 1 recites a tissue puncture-sealing apparatus that has a bioabsorbable plug disposed in the lumen of a tubular member, and also has "a bioabsorbable anchor element disposed within the lumen proximal to the plug" (App. Br. 18 (claim 1)). The other independent claims recite similar devices that also have this feature (*id.* at 23 (claim 28) and 25 (claim 60)).

Zhu describes a tissue puncture-sealing apparatus that includes a relatively thin sponge 80 that contains a hemostatic agent and/or adhesive, the sponge being deployed directly on the outer surface of the punctured vessel while the tissue surrounding the vessel is retracted (Zhu [0055]-[0059]); *see also* Figure 6). Once the sponge is in place on the vessel surface, the retractors and sponge-applying device are removed, and the "surrounding body tissues **96** collapse around the sponge **80** and push member **84**. The push member **84** [which is ultimately also removed] holds the sponge **80** in position while body tissue **96** surrounds the sponge **80** and while the adhesive cures" (*id.* at [0059]).

As the Examiner points out, in one embodiment Zhu's device includes a "lock apparatus **130** [which] is employed to help hold the sponge **80** in

place against the artery wall **98**" (*id.* at [0076]; *see also* Figures 17 and 18). Thus, "the lock apparatus **130** holds the sponge **80** tightly in place adjacent the wound w as shown in **FIG. 18**" (*id.*).

In contrast to Zhu's sponge and lock apparatus, which adhere closely to the punctured blood vessel and are surrounded by the overlying tissue, Cates' device uses a relatively long collagen plug 12 that extends essentially from the surface of the skin to the wall of the punctured vessel, through the intervening punctured tissue, which Cates calls the "access passage AP" (*see, e.g.*, Cates, col. 10, l. 3; *see also* Figure 9).

As Cates explains, once the plug 12 is deployed in the access passage, "[a]s soon as the body fluids contact the plug **12**, it starts to soften and any seepage of blood through the blood vessel puncture BVP serves to start the formation of a coagulum at the exterior end of the puncture BVP" (*id.* at col. 10, ll. 3-7). Ultimately, "[a]fter the physician checks to see if the seal has been affected, the projecting end of the control member **20** can be pulled out through the collagen plug **12** to complete the procedure and leave the collagen plug **12** in place forming the coagulum CAM as seen in FIG. **9**" (*id.* at col. 10, ll. 17-22).

Thus, in contrast to Zhu's vessel-adhering anchor feature, Cates' plug is configured to extend through the tissue adjacent to the punctured vessel all the way through the access passage AP. Given that the express purpose of Zhu's anchor is to ensure close adherence of the hemostatic sponge to the vessel wall, we are not persuaded that an ordinary artisan would have combined such an anchor with a device containing Cates' plug, since Cates' plug is specifically configured to extend far from the vessel wall. Moreover, given that Cates' plug itself effectively acts to anchor the vessel puncture-

sealing coagulum CAM in place (*see id.* at Figure 9), we are further persuaded that the Examiner has not advanced an adequate rationale explaining why an ordinary artisan would have been prompted to deploy Zhu's anchor next to Cates' plug.

We agree with the Examiner that a claim "may be obvious in view of a combination of references, even if the features of one reference cannot be substituted physically into the structure of the other reference." *Orthopedic Equip. Co., Inc. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983).

Ultimately, however, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

Here, for the reasons discussed, we are not persuaded that the cited references would have suggested an apparatus having the claimed combination of features to an ordinary artisan. We therefore reverse the Examiner's obviousness rejection of claims 1, 3-14, 21-28, 31-40, and 60-70 over Cates, Sawhney, and Zhu.

The Examiner also rejected claims 15-20 as obvious over Cates, Sawhney, Zhu, and Vidal (Ans. 5-6). The Examiner cited Vidal as evidence that an ordinary artisan would have considered it obvious to include bioabsorbable plugs, shaped as recited in these dependent claims, in a device such as that described by Cates (*id.*).

However, as the Examiner has pointed to no teaching in Vidal that remedies the deficiencies, discussed above, with respect to the anchor

feature required in each of the independent claims, we reverse this rejection as well.

SUMMARY

We reverse the Examiner's rejection of claims 1, 3-14, 21-28, 31-40, and 60-70 as obvious over Cates, Sawhney, and Zhu.

We also reverse the Examiner's obviousness rejection of claims 15-20 over Cates, Sawhney, Zhu, and Vidal.

REVERSED

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